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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
08/648,092 06/21/1996		06/21/1996	JOHNSTON W. MCAVOY	JOHNSTON W. MCAVOY UNSYD-39709		
24201	7590	12/19/2005		EXAMINER		
FULWIDE			FAY, ZOHREH A			
6060 CENT		3	ART UNIT	PAPER NUMBER		
LOS ANGE		90045	1618			
				DATE MAIL ED. 12/10/2005		

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applic	ation No.	Applicant(s)					
Office Action Summary			3,092	MCAVOY ET AL.					
			ner	Art Unit					
		Zohreh	A. Fay	1618					
Period fo	The MAILING DATE of this communi or Reply	cation appears on	the cover sheet with the	correspondence ad	Idress				
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FO CHEVER IS LONGER, FROM THE MA nsions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this common period for reply is specified above, the maximum state to reply within the set or extended period for reply very reply received by the Office later than three months affect patent term adjustment. See 37 CFR 1.704(b).	AILING DATE OF of 37 CFR 1.136(a). In no unication. tutory period will apply ar will, by statute, cause the	THIS COMMUNICATIO be event, however, may a reply be tind will expire SIX (6) MONTHS from application to become ABANDONI	N. mely filed the mailing date of this c ED (35 U.S.C. § 133).	•				
Status					•				
1)	Responsive to communication(s) filed	d on							
	This action is <b>FINAL</b> . 2b) This action is non-final.								
=	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
-,-	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims	•	,						
· _	_								
-	Claim(s) <u>14-28 and 39-44</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.								
	Claim(s) is/are allowed.								
·	☐ Claim(s) is/are allowed.  ☐ Claim(s) <u>14-28 and 39-44</u> is/are rejected.								
	Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.								
		ion and/or electio	irrequirement.						
Applicati	on Papers								
9)	9) The specification is objected to by the Examiner.								
10)	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	ınder 35 U.S.C. § 119								
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>									
	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PT	TO 048)	Interview Summary Paper No(s)/Mail D						
3) 🛛 Inform	e of Draftsperson's Patent Drawing Review (PT nation Disclosure Statement(s) (PTO-1449 or F r No(s)/Mail Date		5) Notice of Informal F 6) Other:		D-152)				

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Claims 14-28 and 39-41 are presented for examination.

The amendments and remarks filed on September 23, 2005 have been received and entered.

Claims 14-28 and 39-41 are again rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on page 2-4 of the office action of January 26, 2005.

Claims 19-23 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 92/17206 for the reasons set forth on page 4 of the office action of January 26, 2005.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following precedent is believed relevant to the instant case. Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119, F.3d at 1566. The Federal Circuit Court has adopted the standard set forth in the Patent and Trademark Office guidelines for examination of Patent applications under 35 U.S.C. 112 first "written"

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Description" requirement ("Guidelines"), 66 Fed.Reg 1099 (Jan. 5, 2001), which state that a written description can be met by "showing that an invention is complete by disclosure of sufficient detailed, relevant identifying characteristics, "including, inter alia, functional characteristics when coupled with a known or disclosed correlation between function and structure...."Enzo Biochem, inc. v. Gen-Probe inc., 296 F.3d, 316 1324-25 (Fed. Cir. 2002) (quoting guideline, 66 Fed Reg. At 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual content of DNA sequences, this does not preclude extending those reasoning of those cases to chemical structures in general. Univ. of Rochester v.G.D. Searle 7 Co., 249 F. supp. 2d 216, 225 (W.D.N.Y.2003).

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of suitable inhibitors of TGFB. The specification describes only a limited number of inhibitors of TGFB. The instant claims generally recite "one or more inhibitors of TGFB". When functional claims are drawn this broadly, they are inclusive of any TGFB inhibitors, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structure. The instant specification, quite simply, cannot provide direction for using any peptides, proteins or RNA-DNA based structures, in the absence of any identifying characteristics of any kind, e.g. sequences. Accordingly, the instant specification fails to provide an adequate written description of 'one or more inhibitors of TGFB" generally.

Applicant's arguments regarding the 112 rejection have been carefully considered, but are not deemed to be persuasive. Applicant fails to provide information

allowing skilled artisan to ascertain the compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "inhibitors of TGFB", necessitating an exhaustive search for the embodiment suitable to practice the claimed invention. Applicant's arguments and remarks regarding the 102 (b) rejection have also been carefully considered, but are not deemed to be persuasive. The intended use for an old composition does not create a patentably distinct composition. To use an old composition for ophthalmic application does not render the composition new in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

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